



Certificate of Analysis

Paclitaxel Semi-synthetic USP

Catalog Number: PA1005
Lot Number: 0915601
CAS Number: 33069-62-4
Source: Semi-synthetic
Molecular Formula: C₄₇H₅₁NO₁₄
Molecular Weight: 853.91
Storage: ≤ -30°C
Date of Manufacture: July 13, 2016
Retest Date: July 12, 2018

Test	Specification	Result
Appearance	White crystalline powder	Conforms
Assay	97.0 – 102.0%	99.62%
Identification FTIR HPLC	To match reference spectrum Retention time of major peak corresponds to the standard	Conforms Conforms
Specific Rotation	-49.0° to -55.0°	-53.5°
Related Compounds		
Baccatin III	≤ 0.2%	0.024%
10-Deacetylpaclitaxel	≤ 0.5%	Undetected
Photodegradant	≤ 0.2%	Undetected
10-Debenzoylbaccatin III	≤ 0.1%	Undetected
2-Debenzoylpaclitaxel-2-pentenoate	≤ 0.7%	Undetected
10,13-Bissidechainpaclitaxel	≤ 0.5%	Undetected
7-Acetylpaclitaxel	≤ 0.6%	Undetected
7-Tes-paclitaxel	≤ 0.3%	Undetected
13-Tes-baccatin III	≤ 0.1%	Undetected
7-Epipaclitaxel	≤ 0.5%	0.055%
Others	≤ 0.1% (each)	0.04%
Total	≤ 2.0%	0.12%
Organic Volatile Impurities		
Acetone	≤ 5000ppm	350ppm
Hexane	≤ 290ppm	52ppm
Moisture	≤ 4%	0.91%
Heavy Metals	≤ 0.002%	< 0.002%

Approved by:

John Grubb, PhD
Gojira Fine Chemicals, LLC

Date: September 15, 2016



Gojira Fine Chemicals, LLC

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